




LACDMH
LOS ANGELES COUNTY
DEPARTMENT OF
MENTAL HEALTH

DEPARTMENT OF MENTAL HEALTH POLICY/PROCEDURE

SUBJECT USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH	POLICY NO. 500.05	EFFECTIVE DATE 04/14/2003	PAGE 1 of 7
APPROVED BY:  Director	SUPERSEDES 500.9 04/14/2003	ORIGINAL ISSUE DATE	DISTRIBUTION LEVEL(S) 1

PURPOSE

- 1.1 To protect the privacy of Protected Health Information (PHI) of individuals who are participants or subjects in research within the Los Angeles County Department of Mental Health (LACDMH).
- 1.2 To assure all applicable standards and regulations of the Health Insurance Portability and Accountability Act (HIPAA) are enforced as necessary for research within LACDMH.

NOTE: This policy and procedures apply to all LACDMH workforce members who use and disclose PHI in connection with research.

DEFINITION

- 2.1 **“Authorization”** means the signed authorization language used by LACDMH to obtain an individual’s permission prior to using or disclosing that individual’s PHI for purposes that do not fall within the definitions of treatment, payment or health care operation activities or other purposes that do not require the individual’s signature.
- 2.2 **“Institutional Review Board (IRB)”** means a board established in accordance with applicable federal regulations to review research protocols to protect the rights of research participants to minimize their risks related to the research. The Human Subjects Research Committee (HSRC) is designated to review all research proposals involving LACDMH clients, including those projects already approved by outside IRBs, and to assure that all research is carried out within standards and policies of LACDMH.



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- 2.3 **“Human Subjects Research Committee” (HSRC)** means a LACDMH committee which is responsible for the review of all research protocols which include LACDMH clients as research subjects, including those research protocols already approved by an IRB to assure that all research is conducted in accordance with the standards and policies of LACDMH. The HSRC is not an IRB. The HSRC provides an extra level human subjects protection with respect to LACDMH clients.
- 2.4 **“Workforce”** means employees, volunteers, trainees, and other persons whose conduct in the performance of work for a covered entity is under the direct control of such entity, whether or not they are paid by the covered entity.

POLICY

- 3.1 It is the policy of LACDMH to permit use and disclosure of PHI for research purposes, regardless of the source of the funding for the research, only as provided in this policy. LACDMH will permit uses and disclosures for research purposes as follows:
- 3.1.1 If the individual who is the subject of the PHI provides prior authorization.
 - 3.1.2 Without the individual's prior authorization if:
 - 3.1.2.1 An Institutional Review Board (IRB) has approved a waiver of the authorization requirement.
 - 3.1.3 Without the individual's prior authorization under any of the following circumstances:
 - 3.1.3.1 Representations are obtained from the researcher that the use or disclosure of the PHI is solely for the preparation of the research.



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3.1.3.2 Representations are obtained from the researcher that the use or disclosure of the PHI is solely for research on the PHI of decedents.

3.1.3.3 The PHI is de-identified in compliance with HIPAA's de-identification requirements or a limited data set is used (LACDMH Policy No. 500.04, De-Identification of Protected Health Information and Use of Limited Data Sets).

PROCEDURE

4.1 Use and Disclosure of PHI for Research with Authorization

- 4.1.1 When the researcher determines it is feasible (or mandated, in the case of clinical trials) to obtain the individual's authorization, the researcher will undertake to ensure the Authorization for Use or Disclosure of Protected Health Information Form (Attachment 1) discloses how the individual's PHI will be used or disclosed and otherwise contains the information required to be set forth in the HSRC approved Authorization Form.
- 4.1.2 At this time, all subjects must have the capacity to give informed consent. Proxy/surrogate consent may not be used for research conducted within LACDMH or its contract agencies that require authorization by the individual research. Capacity to consent will be determined by a psychiatrist, clinical psychologist or other qualified professional not otherwise involved in the research. Research protocols may not include cognitively impaired individuals lacking capacity to give informed consent in the subject population.
- 4.1.3 For studies including Minors in the subject population, the researcher must ensure that the person signing the Authorization on behalf of the Minor has appropriate authority as the Minor's Personal Representative. Minors who are in the custody of the court (i.e., dependent child or ward status) may have the Authorization signed by the court.



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4.1.4 Certain research protocols may require that the research subject not know the exact nature of the therapeutic intervention. Therefore, it is not required that an individual be provided with access to their PHI while they are participating in a clinical trial. In such cases, the research subject must be informed of this on the individual research Authorization Form and/or on the informed consent form to participate in the research.

4.1.5 If the research subject refuses to sign the research Authorization, he/she may not participate in the clinical trial. The Authorization form must contain a statement to that effect.

4.1.6 When the individual's authorization is obtained, his/her PHI can be used or disclosed in a manner in accordance with the terms of the authorization language. When the researcher wishes to use or disclose PHI for a purpose not set forth in the Authorization Form, the researcher may request another authorization form and present it to HSRC for approval, unless an exception pursuant to this policy applies.

4.2 Use and Disclosure without Authorization

4.2.1 There may be instances where it is not possible or practicable to obtain an Authorization to conduct research, such as in the case of records research. The Department will permit use or disclosure of PHI without authorization when an approval of the waiver of the authorization is provided by HSC.

4.2.2 The HSRC will review the research protocols and the request for a waiver and will issue only such waiver if it determines the following criteria are met:

4.2.2.1 The research cannot practicably be conducted without the waiver.

4.2.2.2 The research cannot practicably be conducted without access to and use of the PHI.



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4.2.2.3 Use or disclosure of PHI involve no more than minimal risk to the privacy of the individual, based on at least one of the following requirements:

- There is an adequate plan to protect the identifiers from improper uses and disclosures;
- There is an adequate plan to destroy the identifiers at the earliest opportunity, unless there is a health or research justification for retention, or unless required by law; or
- There are adequate written assurances from researchers that the PHI will not be further used or disclosed except as required by law, for authorized research oversight, or for other research which would be permitted by HIPAA.

4.2.3 When the HSRC approves the waiver, it will maintain the following documents:

4.2.3.1 Written statement identifying the HSC and the date it approved the waiver

4.2.3.2 Description of the PHI needed.

4.2.3.3 Statement that the HSRC reviewed the waiver under normal or expedited procedures.

4.2.3.4 Signature of the HSRC chair or designee, or

4.2.3.5 Written statement that the criteria for a waiver of the Authorization requirement, as those criteria are described in Section 4.2.2 are met.

4.2.4 Uses and disclosures of PHI authorized by the HSRC may be relied upon as satisfying the minimum necessary requirement, if reasonable.



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4.3 Review of Protected Health Information in Preparation for Research

- 4.3.1 If PHI is needed solely for research, such as to prepare a protocol, LACDMH may permit researchers to access PHI without individuals' prior authorization and without HSRC approval of a waiver of authorization, if the requirements of this Section 4.3 are met.
- 4.3.2 LACDMH must ensure the researchers review and sign Representation of Researcher to Review Protected Health Information held by Los Angeles County Department of Mental Health to Prepare for Research Form (Attachment 2), indicating that the researcher will provide the following representations the HSRC and to LACDMH.
 - 4.3.2.1 Review of PHI will be limited as necessary to prepare for research.
 - 4.3.2.2 The researcher will not remove the PHI and will record it only in de-identified form.
 - 4.3.2.3 Review of the PHI is necessary for the research.
- 4.3.3 The HSRC must approve the request to review PHI in preparation for research.
- 4.3.4 The Department is responsible for ensuring that only those researchers who have signed such a form with the information from Section 4.3.2 will have access to PHI for research preparation.

4.4 Research on Protected Health Information of Decedents

- 4.4.1 In the event that access to PHI is needed solely to conduct research of the PHI of decedents, LACDMH may permit researchers to access PHI without authorization and without HSRC approval of a waiver of authorization if the following requirements are met.



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4.4.1.1 LACDMH must ensure that the researchers review and sign a Representation of Researcher to Review Protected Health Information of Decedents held by Los Angeles County Department of Mental Health Form (Attachment 3). The researcher makes the following representations to the HSRC and to LACDMH.

4.4.1.1.1 Only the PHI of decedents will be reviewed for the research.

4.4.1.1.2 Review of the PHI is necessary for the research.

4.4.1.1.3 At the Department's request, the researcher will provide documentation of death of the individuals whose PHI will be reviewed.

DOCUMENT RETENTION

5.1 Documentation required or completed under this policy shall be retained for at least six (6) years after completion of the research.

AUTHORITY

1. HIPAA, 45 CFR Section 164.508 and 164.512(i)

ATTACHMENT (HYPERLINKED)

1. [Authorization for Use or Disclosure of Protected Health Information](#)
2. [Representation of Researcher to Review Protected Health Information held by Los Angeles County Department of Mental Health to Prepare Research](#)
3. [Representation of Researcher to Review Protected Health Information of Decedents held by Los Angeles County Department of Mental Health](#)